Checklist for Documentation of Informed Consent

45 CFR § 46.117

A. EXCEPT AS PROVIDED IN PARAGRAPH "C" OF THIS SECTION, INFORMED CONSENT SHALL BE DOCUMENTED BY THE USE OF A WRITTEN CONSENT FORM APPROVED BY THE IRB, AND SIGNED BY THE SUBJECT OR THE SUBJECT'S LEGALLY AUTHORIZED REPRESENTATIVE. A COPY SHALL BE GIVEN TO THE PERSON SIGNING THE FORM.	
WRITTEN	The consent form may be either of the following: 1. A **written consent** document that embodies the elements of informed consent required by §46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator should give either the subject or the representative adequate opportunity to read it before it is signed.
DONE ORALLY	2. A **short form written consent** document, stating that the elements of informed consent required by §46.116 have been presented **orally** to the subject or the subject's legally authorized representative. When this method is used, there shall be a **witness** to the oral presentation. Also, the IRB shall approve a **written summary** of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.
WAIVER of req't for signed form	c. An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects, if it finds either: 1. That the only record linking the subject and the research would be the consent document, and the **principal risk** would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or 2. That the research presents **no more than minimal risk** of harm to subjects, and involves no procedures, for which written consent is normally required outside of the research context. In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.